UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,765	05/13/2005	Stefan Golz	Le A 35 838 (004974.01073	9673

22907 7590 01/27/2009

BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
01/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/508,765	GOLZ ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,27,28 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 27, 28, 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's amendment filed on 11/16/2008 has been entered. Claims 2 and 27 are amended. Claim 37 is added. Claims 2, 27, 28, and 32-37 are pending and under consideration.

Withdrawn Objections and/or Rejections

The objection to claim 27 is withdrawn in view of amended claim.

Claim Rejections under 35 U.S.C. § 101 and § 112, 1st Paragraph

(i). 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(ii). Claims 2, 27, 28, and 32-36 are rejected under 35 U.S.C. §101 and § 112, 1st Paragraph because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. New claim 37 is also rejected on the same basis.

(iii). Response to Applicants' argument

Applicants disagree with the office action and argue that a specific utility does not mean a unique utility. Citing case law, Applicants argue that although the specification needs to assert only one credible assertion of specific utility, this does not preclude the

specification from asserting more than one utility. Applicants argue that nothing in the definition of "heart failure" suggests a screening method for a test compound which affects a molecule involved in contraction/relaxation would not be useful for identifying potential therapeutic agents for treating heart failure. Applicants argue that Keitoku et al. discloses a contraction/relaxation effect of FMLP, a ligand which binds to the three FMLP receptors, including FPRL2, in coronary arteries. Applicants argue that this publication supports use of FRPL2 as a target for treating heart failure, which involves a failure of an appropriate rate of pumping. Applicants further argue that a causative link to a heart failure is not required for a particular drug target to be useful for treating heart failure.

Applicants' argument's has been fully considered, but is not deemed to be persuasive for the following reasons. First, a specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research. The assertion that the FRPL2 protein can be used in screening methods to identify potential therapeutic compounds for heart failure does not represent a specific and substantial utility because the specification does not identify a particular disease, such as heart failure, that can be treated; instead, the specification lists a long list of diseases (last paragraph of page 4 and 53-60). Even hear failure further comprises many different pathophysiological states with distinct pathological features (page 55).

Secondly, the mRNA quantification shows expression of FPRL2 in various human tissues, including breast and lung tumors ((Table 1 on page 88). It is noted that in the whole heart, the relative expression of FPRL2 is quite low, with a value of 25. Thus, Table 1 does not show a predominant expression of FPRL2 polypeptide in heart or in cardiomyocytes. More importantly, the expression of FPRL2 does not establish a showing that a modulator of FPRL2 is useful for treating heart failure.

Furthermore, neither prior art nor the instant disclosure establishes that the FPRL2 polypeptide modulates myocardial contractility or an altered activity of the FPRL2 polypeptide leads to heart failure. The specification does not disclose a causative link between the FPRL2 polypeptide and a specific type of heart failure or any particular biological functions of FPRL2 polypeptide that render an agonist or antagonist of FRPL2 useful in treating heart failure. The prior art teaches that FPRL2 is expressed on monocytes and is a chemotactic receptor (Christophe et al., J. Biol. Chem. 276:21585-21593, 2001; in particular page 21586, the 2nd paragraph of left column). Keitoku et al. (J. Mol. Cell. Cardiol. 29:881-894, 1997) teach FMLP produced transient tension changes in human coronary arteries, mainly via the generation of TXA2 and PGI2 and this effect of FMLP appeared to be mediated by the activation of unidentified medial tissue cells which might have functional FMLP receptor homologues (see, e.g., Abstract). Keitoku et al. do not teach modulation of myocardial contractility by the FPRL2 polypeptide of the present invention and do not teach an altered activity of the FPRL2 polypeptide leads to heart failure.

Clearly, further research would be required to determine whether an agonist or an antagonist of the FRPL2 screened by the instantly claimed method can be used to treat heart failure. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Claim Rejections under 35 USC § 112, 2nd paragraph

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 2, 27, 28, and 32-37 are indefinite because they recite "wherein the activity of the FPRL2 is an activity of a G protein coupled receptor". It is unclear what activity is referred since there are hundreds of G protein coupled receptors taught in the literature. The specification also states that the activity of a seven-transmembrane receptor can be measured in a number of ways, not all of which are suitable for any given receptor (page 41, lines 8-10). Since neither the specification nor the claims defines the term unambiguously, rendering the claim indefinite. Claims 27, 28, and 32-36 are rejected as dependent claims from claim 2.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
January 21, 2009